REMARKS

This is a full and timely response to the outstanding Office Action mailed August 3, 2010. Reconsideration of the application and allowance of presently pending claims, are respectfully requested.

A. Present Status of Patent Application

Claims 20, and 22-31 remain pending in the present application. Claim 21 has been cancelled. Claims 20 and 22 have been amended. The amendments to claims 20 and 22 are supported in the present application at least at paragraph [0008] on page 3, lines 13-17.

B. Response to Action

1. Claim Rejections under 35 U.S.C. § 103(a) over Sladek (US 6,014,972) and further in view of Power (US 2002/0002975).

Claims 20, 22-23, and 30 have been rejected under 35 U.S.C. § 103(a) over Sladek and further in view of Power. The analysis of obviousness was set forth in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). In order to establish a *prima facie* case of obviousness, three basic criteria must be met:

> First, there must be some *suggestion or motivation*, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings of the references. Second, there must be a *reasonable expectation of success.* Finally, the prior art reference or combined references must teach or suggest *all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art*, and not based on applicant's disclosure (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); (*emphasis added*).

The Applicant respectfully traverses the rejection as failing at least the first and third elements of the *Graham* test.

The rejection of claim 20 is discussed first. Regarding the first element of the *Graham* test, the Examiner has argued that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the pulmonary drug delivery system disclosed by Sladek, by utilizing an ultrasonic nebulizer as taught by, Power in order to obtain a device that could deliver smaller particles to a users lungs thereby increasing the amount of medicament absorbed in to the lung tissues." (*See* Office Action, dated Aug. 3, 2010, page 3 - emphasis added). However, Sladek teaches away from a combination with Power since the nebulizer in Power does not use dry particles as in Sladek. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). The Examiner is asked to note the following teachings of Sladek:

> The invention relates to a device for delivering dry medication particles from an MDI (metered dose inhaler) or dry powder medication measuring device to an intubated patient through a ventilator circuit or an anesthesia device, and more particularly to a device which reduces or minimizes absorption of humidity by minute, dry, light medication particles. (*See* Sladek, col. 1, lines 7-13).

Sladek discloses a system for the delivery of dry powder medication to a patient, whereas the claimed invention requires "introducing an aerosolized liquid medicament into the second gas flow by a vibrating aperture nebulizer coupled to the respiratory circuit." (emphasis added). Although the recitation of "a vibrating aperture nebulizer coupled to the respiratory circuit" in claim 20 should be sufficient to limit claim 20 to the introduction of a liquid medicament, in an attempt to simplify prosecution, the Applicant has amended claim 20 to require introduction of a liquid medicament. In contrast, Sladek specifies the use of an MDI and "dry" formulations:

> The inspiratory air stream 1B carries the dry, light medication particles and the bolus of dry air carrying them through endotracheal tube 7 all the way into the intended therapeutic sites within the patient's lungs, to minimize the loss of the medication dose due to medication particles becoming surrounded and weighted by droplets of water which impinge on the walls of the inspiratory path and fall out of the inspiratory stream before reaching the therapeutic sites in the patient's lungs. (*See* Sladek (Detailed Description of Preferred Embodiments).

The present claims do not specify an MDI and dry formulations, as they instead require "introducing an aerosolized liquid medicament." Since Sladek teaches away from liquid medicament, and Power provides no support for being used in a system designed for dry formulations, it is improper to combine the references, in violation of the rule in *In re Grasselli, supra*. Accordingly, the Applicant respectfully requests withdrawal of the rejection. Reconsideration and allowance of claim 20 is respectfully requested.

Regarding the third element of the *Graham* test, even if Sladek is combined (improperly) with Power, the combination does not teach or suggest all the claim limitations. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

The Examiner has contended that Sladek discloses and/or teaches "a pressure-generating circuit (1 and 32) and a respiratory circuit (20, 22, 23, 26) adapted to be coupled to a patient interface device (7), wherein the pressure generating circuit (1 and 32) contains a first gas flow (1B typically from 24-125 liters per minute as described on col. 5, lines 60-66) of sufficiently high-volume to maintain positive pressure in the system and wherein the respiratory circuit (20, 22, 23, 26) contains a second gas flow (8-15 liters per minute as described on col. 5, lines 60-66) of lower volume than the first

gas flow." (See Office Action, dated Aug. 3, 2010, page 2).

Claim 20 requires that the respiratory circuit which has a lower gas flow, and not the pressure-generating circuit which has a higher gas flow, be coupled to the patient interface device. As shown in Fig. 4 from the Sladek reference, this is not the case.

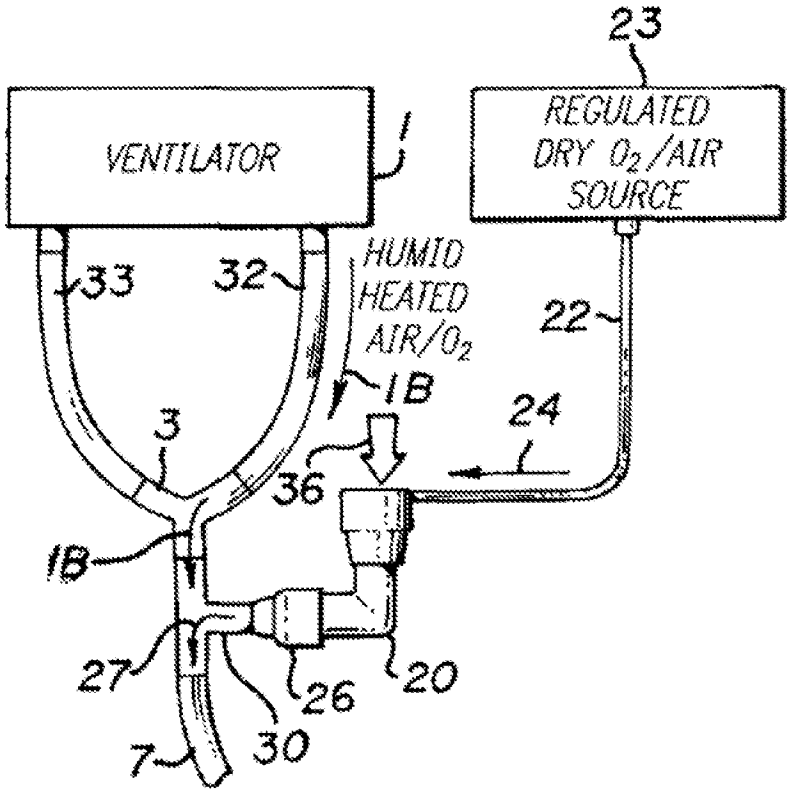

FIG. 4

The respiratory circuit, as recited in claim 20, is a "respiratory circuit adapted to be coupled to a patient interface device." In contrast, as can be seen from the included Fig. 4 from Sladek, the portion of the Sladek device cited by the Examiner as the respiratory circuit (20, 22, 23, 26) is not adapted to be coupled to a patient interface device (7). Rather, it is the pressure generating circuit (1 and 32) having higher flow (1B), into which the respiratory circuit (20, 22, 23, 26) is attached, which is adapted to be coupled to the patient interface device (7). Accordingly, the flow to the patient interface device (7) will be the higher gas flow, not the lower gas flow as required by claim 20. Therefore, the combination of art fails to disclose, teach, or suggest *all the claim limitations.* Accordingly, the rejection violates the third element of the *Graham* test. Reconsideration and allowance of claim 20 is respectfully requested.

Regarding the rejection of claim 22, the Examiner has argued that Power discloses a reservoir having one unit dose of medicament. However, Power discloses simply that "Information regarding, for example, the type of medication contained within the medication cup 2 or suitable dosages, or periods in which to use the medication may be provided on the sealing sheet 19. The information may be, for example, printed onto the sheet 19, or affixed with a label. The information may be, for example, in bar code format." (*See* Power, [0072]). The mere disclosure of the terms 'suitable dosages' does not obviate a claim directed to "a reservoir having a capacity equal to one unit dose of liquid medicament" or that "substantially all of the contents of the reservoir [are] delivered to the patient's respiratory system," as required by claim 22.

First, Power fails to disclose or teach that the medication cup may contain one unit dose of a medicament. Instead, Power teaches that what may constitute a dose may be printed on a label, presumably for use in administering the proper amount of medicament to the medication cup. However, this source of human error is eliminated by the claimed invention in claim 22, since the reservoir in claim 22 fits exactly one unit dose of medicament, and no measuring is needed to determine the quantity to be administered to the reservoir.

In addition, Power fails to disclose or teach that the medication cup is completely depleted after treating a patient. Instead, the medication cup could have any amount of medicament added, and treatment may last for a variable length of time. This introduces another source of human error, in that the medicament could be administered for too short or too long of a time, thereby rendering the treatment less effective and/or dangerous.

For these reasons, the rejection of claim 22 violates the third element of the *Graham* test, as Power does not render claim 22 obvious after the application of Sladek to claim 20. Accordingly, withdrawal of the rejection of claim 22 is respectfully requested.

Regarding the rejection of claim 23, this claim depends from claim 20 and therefore incorporates all the limitations of claim 20. Claim 20 is believed to be allowable over

Sladek in view of Power. Therefore, due to its dependence, claim 23 is believed to be allowable over the combination of art. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and allowance of claim 23 is respectfully requested.

Regarding the rejection of claim 30, the rejection is improper due to the dependence of claim 30 on claim 24, which, as argued later, is believed to be allowable. Therefore, claim 30 is also believed to be allowable. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and allowance of claim 30 is respectfully requested.

2. Claim Rejections under 35 U.S.C. § 103(a) over Sladek and Power and further in view of Merrill (US 3,715,432).

Claims 24-30 have been rejected under 35 U.S.C. § 103(a) over Sladek and Power and further in view of Merrill. The analysis of obviousness was set forth in *Graham*, *supra*.

Regarding the rejection of claim 24, the Examiner contends that "the combined references disclose a device and method of using a device as claimed, but lack the specific teaching of using a liquid surfactant, as claimed. Merrill teaches aerosolizing aqueous dispersions of lecithin (also known as phosphatidylcholine, a well known phospholipid used in the respiratory arts for treating lung disorders) using an ultrasonic nebulizer." (See Office Action, dated Aug. 3, 2010, page 4).

However, even assuming that Merrill teaches the introduction of a liquid surfactant, which the Applicant is not conceding, the combination of art does not teach or suggest all the claim limitations, in violation of the third element of the *Graham* test. Particularly, claim 24 requires "providing a CPAP system having a pressure-generating circuit with a first gas flow of sufficiently high volume to maintain continuous positive airway pressure in the system, a respiratory circuit connecting the pressure-generating

circuit to a patient interface device, wherein the respiratory circuit contains a second gas flow of lower volume than said first gas flow." (*See* claim 24, emphasis added).

The Examiner has contended that Sladek teaches "a pressure-generating circuit (1 and 32) and a respiratory circuit (20, 22, 23, 26) adapted to be coupled to a patient interface device (7), wherein the pressure generating circuit (1 and 32) contains a first gas flow (1B typically from 24-125 liters per minute as described on col. 5, lines 60-66) of sufficiently high-volume to maintain positive pressure in the system and wherein the respiratory circuit (20, 22, 23, 26) contains a second gas flow (8-15 liters per minute as described on col. 5, lines 60-66) of lower volume than the first gas flow." (See Office Action, dated Aug. 3, 2010, page 2).

Claim 24 requires that the respiratory circuit which has a lower gas flow, and not the pressure-generating circuit which has a higher gas flow, be coupled to the patient interface device. As shown in Fig. 4 from the Sladek reference, this is not the case.

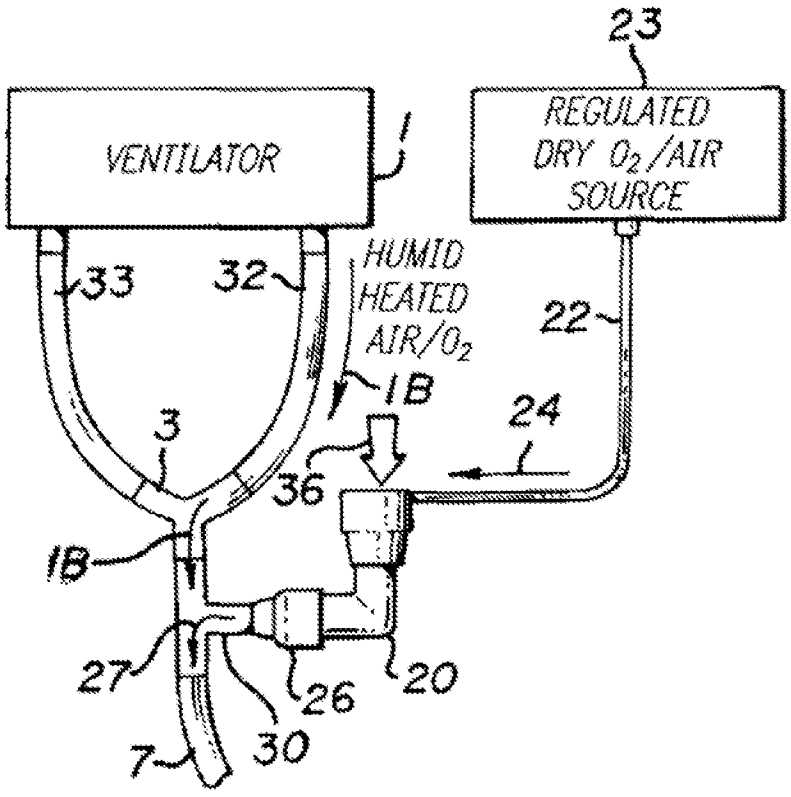

FIG. 4

The respiratory circuit, as recited in claim 24, is a "respiratory circuit connecting the pressure-generating circuit to a patient interface device." In contrast, as can be seen

from the included Fig. 4 from Sladek, the portion of the Sladek device cited by the Examiner as the respiratory circuit (20, 22, 23, 26) is not adapted to be coupled to a patient interface device (7). Rather, it is the pressure generating circuit (1 and 32) having higher flow (1B), into which the respiratory circuit (20, 22, 23, 26) is attached, which is adapted to be coupled to the patient interface device (7). Accordingly, the flow to the patient interface device (7) will be the higher gas flow, not the lower gas flow as required by claim 24. Therefore, the combination of art fails to disclose, teach, or suggest *all the claim limitations.* Accordingly, the rejection violates the third element of the *Graham* test.

However, even assuming, *arguendo,* that it would have been obvious to combine the teachings of Sladek and Power as proposed by the Examiner, such combination does not result in the invention of claim 24 because the combination fails to include the step of introducing the aerosolized surfactant into the CPAP system at a location outside the high-volume gas flow of the pressure-generating circuit of the CPAP system, thereby avoiding the dilution of the aerosolized surfactant and increasing the amount of aerosolized surfactant delivered to the patient's respiratory system. For this reason, the rejection of claim 24 violates the third element of the *Graham* test, and must be withdrawn. Reconsideration and allowance of claim 24 is respectfully requested.

Regarding the rejection of claims 25-30, the claims depend from claim 24, which, as argued above, is believed to be allowable over the combination of art. Therefore, due to their dependence, claims 25-30 are also believed to be allowable. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and allowance of claims 25-30 is respectfully requested.

In the event a telephone conversation would expedite the prosecution of this application, the Examiner may reach the undersigned at (510) 923-4298. For payment of any additional fees due in connection with the filing of this paper, the Commissioner is authorized to charge such fees to Deposit Account No. 19-0134 (Order No. 53428-US-NP).

Respectfully submitted,

By: /Michael J. Mazza/ Date: November 2, 2010
Michael J. Mazza
Reg. No. 30,775

Novartis Pharmaceuticals Corporation
Novartis Vaccines and Diagnostics, Inc.
Intellectual Property M/S X-100B
4560 Horton Street
Emeryville, CA 94608
USA